



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0525; FRL-10020-23]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on multiple commodities that are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0525, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff

continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit

<https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You

must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0525 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0525, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8779) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide spinosad, including its metabolites and degradates in or on the raw agricultural commodities dragon fruit at 1.5 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 2.0 ppm; kohlrabi at 2.0 ppm; vegetable, leafy, group 4-16 at 10.0 ppm; celtuce at 10.0 ppm; fennel, Florence, fresh leaves and stalk at 10.0 ppm; leaf petiole vegetable subgroup 22B at 10.0 ppm; and berry, low growing, except strawberry, subgroup 13-07H at 0.01 ppm. The petition also requested to amend 40 CFR 180.495 by removing the following spinosad tolerances: *Brassica*, head and stem, subgroup 5A at 2.0 ppm; *Brassica*, leafy greens, subgroup 5B at 10 ppm; vegetable, leafy, except *Brassica*, group 4 at 8 ppm; and cranberry at 0.01 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing several tolerances at different levels than requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for

which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spinosad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spinosad follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for spinosad, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to spinosad and established tolerances for residues of that chemical. EPA is incorporating previously published sections that remain unchanged from those rulemakings as described further in this rulemaking.

Toxicological Profile. For a discussion of the Toxicological Profile of spinosad, see Unit III.A. of the September 19, 2019 rulemaking (84 FR 49195) (FRL-9995-90).

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the September 29, 2019 rulemaking.

Exposure Assessment. Much of the exposure assessment remains unchanged from the previous rulemaking, although the new exposure assessment incorporates the additional dietary exposure from the petitioned-for tolerances. The residue levels, percent crop treated, and estimated drinking water concentrations used in the exposure assessment remain the same and are discussed in Unit III.C. of the September 29, 2019 rulemaking. Moreover, there have been no changes to residential exposures, so the Agency's approach for assessing residential (non-occupational, non-dietary exposures) is also discussed in that same Unit. Finally, the Agency's conclusions about cumulative effects remain the same as in that Unit.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the FQPA SF were reduced from to 1X. The reasons for that decision are articulated in Unit III.D. of the August 8, 2018 rulemaking.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute analysis was not conducted as toxicological effects attributable to a single dose were not identified. Chronic dietary risks are below the Agency's level of

concern of 100% of the cPAD: children 1 to 2 years old are the population subgroup with the highest exposure estimate at 72% of the cPAD. The short-term aggregate MOE (food, water, and residential) is 200 for children 1 to less than 2 years old and 780 for adults. These MOEs do not exceed the target level of concern of 100. The short-term aggregate risk assessment is protective of intermediate-term exposure as the short-term and intermediate-term PODs are identical. EPA has also concluded that spinosad is not expected to pose a cancer risk to humans based on the lack of evidence of carcinogenicity in the database.

Determination of Safety. Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to spinosad residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Spinosad. Summary of Residue Chemistry Data and Human Health Risk Assessment for the Establishment of a Tolerance Without U.S. Registration on Tea." dated March 6, 2019 in docket ID EPA-HQ-OPP-2018-0525 and the document titled "Spinosad and Spinetoram. Human Health Risk Assessment for Proposed Use on Dragon Fruit (Pitaya); Crop Group Expansion for Berry, Low Growing, Except Strawberry, Subgroup 13-07H; and Crop Group Conversions for Vegetable, Brassica, Head and Stem, Group 5-16; Brassica, Leafy Greens, Subgroup 4-16B; Leaf Petiole Vegetable Subgroup 22B; Leafy Greens Subgroup 4-16A; Celtuce; Fennel, Florence, Fresh Leaves and Stalk; and Kohlrabi." dated February 12, 2021 in docket ID number EPA-HQ-OPP-2019-0525.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the September 29, 2019 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs established for dragon fruit, celtuce, and fennel, Florence, fresh leaves and stalk.

The U.S. tolerances for kohlrabi; vegetable, *Brassica*, head and stem, group 5-16; and vegetable, leafy, group 4-16 are harmonized with the Codex MRLs.

The Codex MRL for the leaf petiole vegetable subgroup 22B is 2 ppm while the U.S. tolerance is 8 ppm. Harmonization is not possible because decreasing the U.S. tolerance to harmonize with the Codex MRL would put U.S. growers at risk of having violative residues despite legal use of the pesticide according to the label.

The U.S. tolerance on the berry, low growing, except strawberry, subgroup 13-07H is 0.04 ppm, and the Codex MRL is 0.02 ppm. EPA is not harmonizing this tolerance with Codex because EPA's spinosad tolerance is based on available residue data for the toxicologically equivalent spinetoram, which supports the higher tolerance.

C. Revisions to Tolerances

Based upon review of the data supporting the petition, EPA is establishing tolerance levels consistent with Organization for Economic Cooperation and Development (OECD) Rounding Class Practice.

The tolerance for berry, low growing, except strawberry, subgroup 13-07H is being established at 0.04 instead of 0.01 as proposed. Due to the toxicological equivalence and similar use patterns of spinosad and spinetoram, EPA allows for the bridging of field trial residue data between the two chemicals when consistent with the application rates. The available data supports establishing the higher tolerance for this subgroup.

The tolerances for the leaf petiole vegetable subgroup 22B, celtuce, and fennel, Florence, fresh leaves and stalk are being established at 8 ppm rather than 10 ppm as proposed. This is so the tolerance stays harmonized with Canada, which is a major export market for these commodities.

V. Conclusion

Therefore, tolerances are established for residues of spinosad in or on berry, low growing, except strawberry, subgroup 13-07H at 0.04 ppm; celtuce at 8 ppm; dragon fruit at 1.5 ppm; fennel, Florence, fresh leaves and stalk at 8 ppm; kohlrabi at 2 ppm; leaf petiole vegetable subgroup 22B at 8 ppm; vegetable, *Brassica*, head and stem, group 5-16 at 2 ppm; and vegetable, leafy, group 4-16 at 10 ppm.

Additionally, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; cranberry; and vegetable, leafy, except *Brassica*, group 4.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled

“Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances and modifications in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal

Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 5, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.495, amend the table in paragraph (a) as follows:

- i. Add a heading to the table;
- ii. Add alphabetically an entry for “Berry, low growing, except strawberry, subgroup 13-07H”;
- iii. Remove the entries for “*Brassica*, head and stem, subgroup 5A”; and “*Brassica*, leafy greens, subgroup 5B”;
- iv. Add alphabetically an entry for “Celtuce”;
- v. Remove the entry for “Cranberry”;
- vi. Add alphabetically entries for “Dragon fruit”; “Fennel, Florence, fresh leaves and stalk”; “Kohlrabi”; “Leaf petiole vegetable subgroup 22B”; and “Vegetable, *Brassica*, head and stem, group 5-16”;
- vii. Remove the entry for “Vegetable, leafy, except *Brassica*, group 4”; znc
- viii. Add alphabetically an entry for “Vegetable, leafy, group 4-16”.

The additions read as follows:

§ 180.495 Spinosad; tolerances for residue.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	* *
Berry, low growing, except strawberry, subgroup 13-07H	0.04
* * * * *	* *
Celtuce	8
* * * * *	* *
Dragon fruit	1.5
Fennel, Florence, fresh leaves and stalk	8
* * * * *	* *
Kohlrabi	2
Leaf petiole vegetable subgroup 22B	8
* * * * *	* *
Vegetable, <i>Brassica</i> , head and stem, group 5-16	2
Vegetable, leafy, group 4-16	10
* * * * *	* *

* * * * *

